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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,412	01/29/2004	Stephen A. Johnston	UTSD:681USC1	2869

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EXAMINER

LIU, SUE XU

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/767,412

Applicant(s)

JOHNSTON ET AL.

Examiner

Sue Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 41-63 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 8/02/05
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Status

The preliminary amendment filed on 01/29/2004 has been entered. The preliminary amendment canceled the original Claims 1-40. New Claims 41-63 filed on 1/29/2004 are currently pending.

It has been noted that the applicants have canceled Claims 1-40, however, a previous Election/Restriction requirement regarding Claims 1-40 was mailed on 7/21/2005, which will be withdrawn. A new restriction addressing Claims 41-63 is set forth below.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 41-63 in parts, drawn to a method of vaccinating a subject comprising administering a nucleic acid, classified variously, for example, in class 536, subclass 23.1.
 - II. Claims 41-63 in parts, drawn to a method of vaccinating a subject comprising administering an antigen, classified variously, for example, in class 530, subclass 300.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Groups I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

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different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of Groups I and II are distinct because they use different steps, require different reagents and/or will produce different results. The method of Group I requires “a nucleic acid”, which is a reagent and/or steps that may not be required by Group II methods. Group II method requires a materially different product, an antigen, which is a reagent and/or step that are not required by Group I. The required product for each Group I (a nucleic acid) and Group II (an antigen) is structurally and functionally different from each other. Thus, restriction is proper.

Therefore, these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter. Even though some of the groups are classified in the same class/subclass, this has no effect on the non-patent literature search. The different methods and products will require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches will be coextensive. Therefore, these do create an undue search burden, and restriction for examination purposes as indicated is proper.

Species Election

1. This application contains claims directed to the following patentably distinct species of the claimed invention.

Applicants are requested to further elect a single ultimate species for each of the following:

A.) A single species of an animal. (e.g. mouse)

B.) A single species of a subject. (e.g. mouse)

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C.) A single species of a pathogen selected from the categories of a virus, a yeast, a mold, a algae, a protoza **OR** a bacterial cell. Applicants are further requested to select a single ultimate species of a specific species from each of the categories, e.g. adenovirus for virus; *Mycoplasma pulmonis* for bacterial cell.)

D.) A single species of a host cell selected from the categories of either bacterial **OR** mammalian host cell. Applicants are further requested to select a single ultimate species from each of the categories, e.g. *E. coli*. for bacterial host cell; Hela for mammalian host cell.

E.) A single species of a mammalian gene encodes a fusion protein selected from either ubiquitin **OR** human growth hormone.

F.) A single specie of a promoter for expression in a mammalian cell as defined by the said promoter's specific nucleic acid length and sequence.

G.) A single species of a signal sequence.

H.) A single range of DNA fragment size selected from the range of 100 to 1000bp. (e.g. about 400bp.)

The species are distinct, each from the other, because their structure and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purpose as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. No matter which group Applicants elect, Applicants should identify which claims they believe are generic for each of the corresponding species sets A.)-H.), and which claims read on a particular species within the species sets A.)-H.) For example, Applicants' reply might state "...claim X is generic to the elected species of species sets A.), C.) and E.), but reads on the particular elected species for species sets B.) and D.)" Should a given species not pertain to Applicants' elected group, Applicants should indicate accordingly. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sue Liu
Art Unit 1639
8/02/05


PADMA SHRI PONNALURI
PRIMARY EXAMINER